IEC 60601-2-31

Edition 2.0 2011-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

Appareils électromédicaux –
Partie 2-31: Exigences particulières pour la sécurité de base et les performances essentielles des stimulateurs cardiaques externes à source d'énergie interne

IEC 60601-2-31:2008/A1:2011

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FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62D/918/FDIS	62D/931/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

The purpose of this amendment is to address comments received during the process of harmonizing the standard in Europe, update several references to defined terms that were not printed in SMALL CAPS, and improve terminology usage.

INTRODUCTION

*Replace the term "*IMPLANTABLE*" in the first and third lines of the third paragraph with the same term in normal case*

Replace the defined terms "pacemaker" and "patient" in the fourth line of the fifth paragraph with the same terms in SMALL CAPS.

201.1.1 Scope

Replace the second paragraph with:

This standard applies to PATIENT CABLES as defined in 201.3.109, but does not apply to LEADS as defined in 201.3.106.

Delete the third paragraph.

In the fifth paragraph, replace the defined term "active implantable medical devices" with the same term in SMALL CAPS.

201.1.2 Object

Replace "AS DEFINED IN" in the second line with the same words in normal case.

Replace definition 201.3.105 with:

201.3.105
EXTERNAL PACEMAKER
CARDIAC PACEMAKER consisting of a NON-IMPLANTABLE PULSE GENERATOR and PATIENT CABLE(S) (if used)

201.3.106

Replace the defined term "patient's" in the second line with the same term in SMALL CAPS.

Replace definition 201.3.107 with:

201.3. 107
MAXIMUM TRACKING RATE
maximum PULSE RATE at which the NON-IMPLANTABLE PULSE GENERATOR will respond on a 1:1 basis to a triggering signal

[ISO 14708-2:2005, definition 3.3.18 modified]

201.3.108

Replace the defined term "pulse" in the second line of the definition with the same term in small caps.

201.4.3.101

Replace "PERFORMACNE" with "PERFORMANCE".

201.4.10.2 Supply mains for ME EQUIPMENT and ME SYSTEMS

Replace the defined term "Supply mains" in the title with the same term in SMALL CAPS.

201.7.9.2.2 * Warning and SAFETY notices

Replace the term "pulse generator" with "NON-IMPLANTABLE PULSE GENERATOR" in three places in item 201.7.9.2.2 aa).

Replace the term "external pulse generator" with "NON-IMPLANTABLE PULSE GENERATOR" in item 201.7.9.2.2 ff).

Replace the defined terms "patient", "lead", "leakage current", "manufacturer", " non-implantable pulse generator", "patient cable" and "supply mains" with same terms formatted in SMALL CAPS in items 201.7.9.2.2 bb), cc), dd), ee), ff) and gg).

201.7. 9.2.4 * Electrical power source

*Replace the defined term "*primary battery*" in the second paragraph with the same term in SMALL CAPS.*

201.7.9.2.13 Maintenance

*Replace the term "*EQUIPMENT*" in the final dashed item with "ME EQUIPMENT".*

201.8.5.5 Defibrillation-proof applied parts

Replace the subclause title with:

201.8.5.5 DEFIBRILLATION-PROOF APPLIED PARTS

201.8.5.5.1

Add Note:

NOTE ANSI/AAMI PC69:2007 is being adopted as ISO 14117.

201.8.7.3 * Allowable values

*In the requirement, replace "*for both d.c. and a.c.*" with "*for d.c.*".*

Add note:

NOTE Where the a.c. component of the current is intended to produce a physiological effect, it is therefore outside the definition of PATIENT AUXILIARY CURRENT.

201.8.7.4.8 Measurement of the PATIENT AUXILIARY CURRENT

Replace test method with the following text:

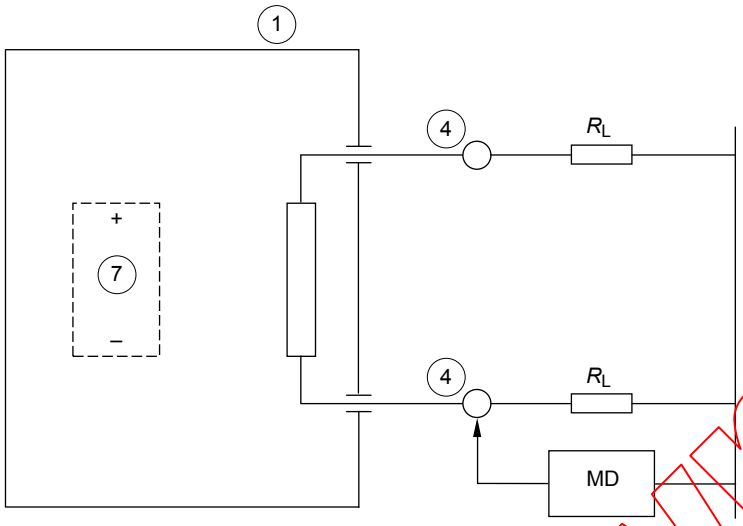
For measurement of the PATIENT AUXILIARY CURRENT, the ME EQUIPMENT is connected as shown in Figure 201.101. Each PATIENT CONNECTION is connected to a common bus through a 500 Ω ± 1% load resistor (R_L). Using a measuring device (MD) consisting of a DC voltmeter, resolution better than 2 μV, fed through a low pass filter with a time constant of at least 10 s, measure the average direct voltage across each low resistor. Steady state condition shall be reached before the measurement is made.

The NON-IMPLANTABLE PULSE GENERATOR shall be set to the nominal settings recommended by the manufacturer (i.e., the factory recommended settings) but with the PULSE AMPLITUDE and PULSE DURATION programmed to the highest available settings.

NOTE The low pass filter can be implemented by a four-element RC filter with elements built from 1 MΩ resistors and 10 μF metalized polypropylene capacitors. The input resistance of the dc voltmeter should be ≥ 400 MΩ.

Figure

Replace the existing Figure 201.101 with the following:



Legend

(1)	ME EQUIPMENT ENCLOSURE
(4)	PATIENT CONNECTIONS
(7)	INTERNAL ELECTRICAL POWER SOURCE
R_L	Load resistor
MD	Measuring device (see 201.8.7.4.8)

201.11.6.5 * Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Replace the requirement with:

The ME EQUIPMENT shall be so constructed that the ingress of liquids (accidental wetting), shall not result in an unacceptable RISK.

201.12.1.101 * ME EQUIPMENT PARAMETERS

Replace the defined term "pulse" in two places in the fifth paragraph with the same term in SMALL CAPS.

201.12.4.1 * Intentional exceeding of safety limits

*In the requirement, replace the reference to "*12.4.103*" by "*201.12.4.103*".:*

201.12.4.102 * Protection against a low battery condition

Replace the term "EQUIPMENT" in the first line of the first paragraph with ME EQUIPMENT.

202.6.2.2 Electrostatic discharge (ESD)

202.6.2.2.1 * Requirements

Replace the defined term "operator" in the fourth dashed item with the same term in SMALL CAPS.

Annex AA – Particular guidance and rationale

Table AA.1 – EXTERNAL PACEMAKER HAZARD inventory

In column 2, row 18, change 'tampering' to 'maladjustment' as follows:

High rate	Fault	Rate limit (runaway protection)	201.12.4.103
	Maladjustment	Protective means	201.12.4.101
	Temporary high rate	Protective means	201.12.4.1
	Atrial tachyarrhythmia	MAXIMUM TRACKING RATE	201.12.4.105

Replace "leakage current" and "patient auxiliary current" in Table AA.1 with same terms in SMALL CAPS.

AA.2 Rationale for particular clauses and subclauses

Subclause 201.1.1 – Scope

Delete the third bullet.

*Replace the defined term "*pulse generator*" in the second line of the paragraph following the bulleted list with "*NON-IMPLANTABLE PULSE GENERATOR*".*

Clause 201.3 – Terms and definitions

Delete the last sentence in the last paragraph.

Clause 201.6.2 – Protection against electric shock

Delete the first paragraph.

Subclause 201.7.2.102 – ME EQUIPMENT intended for DUAL CHAMBER application

*Replace "*INSTRUCTIONS FOR USE*" in the third line with the same term in normal case.*

*Replace the defined term "*lead*" in the fourth line with same term in SMALL CAPS.*

Subclause 201.7.2.104 – Battery compartment

*Replace the defined term "*operator*" in the fifth line with the same term in SMALL CAPS.*

Subclause 201.7.4.102 – Control or indicator for pulse rate

*Replace the defined term "*pulse rate*" in the title with the same term in SMALL CAPS.*

Subclause 201.7.4.103 – Control for selecting pacing mode

*Replace the defined term "*pulse generator*" in the first line with "NON-IMPLANTABLE PULSE GENERATOR".*

Subclause 201.7.9.2.2 bb)

Delete the first sentence.

*Replace the defined term "*lead*" in the third line with same term in SMALL CAPS.*

Subclause 201.7.9.2.2 cc) and **dd)**

*Replace the term "*EQUIPMENT*" in the third line with "*ME EQUIPMENT*".*

Subclause 201.7.9.2.2 ff)

Replace the term "EXTERNAL PULSE GENERATOR" in the second line with "NON-IMPLANTABLE PULSE GENERATOR".

*Replace the defined terms "*pulse*" and "*patient*" in the seventh line with the same terms in SMALL CAPS.*

Subclause 201.7.9.2.2 gg)

*Replace the defined terms "*pulse*" in the first line with the same terms in SMALL CAPS.*

Replace the term "EXTERNAL PULSE GENERATOR" in the second line with "NON-IMPLANTABLE PULSE GENERATOR".

Replace the term "equipment" *in the eighth line with "*ME EQUIPMENT*".*

Subclause 201.7.9.2.4 – Electrical power source

*Replace the defined term "*risks*" in the second line of the second paragraph with the same term in SMALL CAPS.*

Subclause 201.7.9.2.5 aa)

*Replace the term "*pulse generator*" in the first line with "*NON-IMPLANTABLE PULSE GENERATOR*".*

Subclause 201.8.7.4.1 aa)

*Replace the defined term "*pulse*" in two places with the same terms in SMALL CAPS.*

Subclause 201.8.7.4.8 – Measurement of the PATIENT AUXILIARY CURRENT

Replace the defined term "procedure" in the first paragraph with same term in SMALL CAPS.

Delete the second paragraph.

Subclause 201.12.1.101 – ME EQUIPMENT parameters

*Replace the defined term "*pacemakers*" in the second line of the first paragraph with the same term in* SMALL CAPS.

*Replace the term "*EQUIPMENT*" in the third line of the second paragraph with "*ME EQUIPMENT*".*

Subclause 201.12.1.102 – PULSE AMPLITUDE

*Replace the defined term "*lead*" in the first line with same term in* SMALL CAPS.

Subclause 201.12.4.101 – Protection against accidental change of controls and tampering

Replace the paragraph with:

Maladjustment of the controls can result in a HAZARDOUS SITUATION; therefore appropriate steps should be taken to reduce this possibility.

Subclause 201.15.101 – Output indicator

*Replace the defined term "*pulse*" in the second line with the same term in* SMALL CAPS.

Subclause 202.6.2.2.1 – Requirements

*Replace the defined term "*operator*" in the sixth line of the first paragraph with the same term in* SMALL CAPS.

*Replace the term "*EQUIPMENT*" in the second line of the second paragraph with "*ME EQUIPMENT*".*

*Replace the defined term "*operator*" in the eighth line of the third paragraph with the same term in* SMALL CAPS.

Index of defined terms used in this particular standard

*Following the term "*CLASS II*" insert:*

DEFIBRILLATION-PROOF APPLIED PART ..... IEC 60601-1:2005, 3.20

*Following the term "*HAZARD*" insert:*

HAZARDOUS SITUATION ..... IEC 60601-1:2005, 3.40

*Following the term "*IMMUNITY TEST LEVEL*" insert:*

IMPLANTABLE PULSE GENERATOR ..... ISO 14708-2:2005, 3.3.1

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